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Substitute for form 1449A/B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Complete if Known

Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Tedd Ware Carlos A. [Signature]
Attorney Docket Number	402076-SKYE PHARMA

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Sheet 1 of 13

U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
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Examiner Signature	[Signature]	Date Considered	5/9/05
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- * A concise statement of relevance is being submitted in lieu of a translation. 37 CFR 1.98(a)(3).
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Application Number	09/281,430
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First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number 09/281,430
Filing Date March 30, 1999
First Named Inventor INDU PARIKH
Group Art Unit 1615
Examiner Name Todd Ware
Attorney Docket Number 402076 SKYEPHARM

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U.S. PATENT DOCUMENTS

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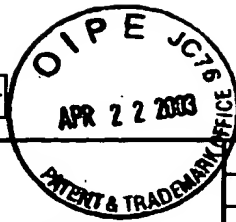
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Application Number 09/281,430
Filing Date March 30, 1999
First Named Inventor INDU PARIKH
Group Art Unit 1615
Examiner Name Todd Ware
Attorney Docket Number 402076 SKYEPHARM

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U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date if Appropriate
		Application or Patent Number	Kind Code			
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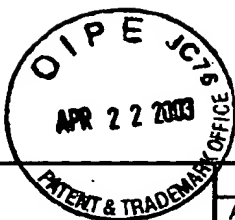
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 5 of 13

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Application Number	09/281,430
Filing Date	March 30, 1999
First Named Inventor	INDU PARIKH
Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

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U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
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Substitute for form 1449A/B/PTO			Compleat if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	09/281,430	
			Filing Date	March 30, 1999	
			First Named Inventor	INDU PARIKH	
			Group Art Unit	1615	
			Examiner Name	Fodd Ware Carlos Azpura	
Sheet	6	of	13	Attorney Docket Number	402076 SKYEPHARMA

U.S. PATENT DOCUMENTS

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		Application or Patent Number	Kind Code			
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Examiner Signature	<i>[Signature]</i>	Date Considered	5/4/03
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First Named Inventor INDU PARIKH
Group Art Unit 1615
Examiner Name Todd Ware
Attorney Docket Number 402076 SKYEPHARM

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U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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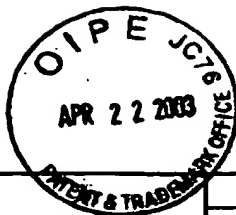
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	09/281,430	
			Filing Date	March 30, 1999	
			First Named Inventor	INDU PARIKH	
			Group Art Unit	1615	
			Examiner Name	Todd Ware	
Sheet	8	of	13	Attorney Docket Number	402076 SKYEPHARMA

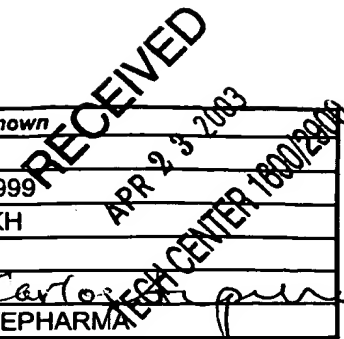
U.S. PATENT DOCUMENTS

Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
SA	A 2 3 4	6267989		Liversidge et al.	7/31/2001	
	A 2 3 5	6270806		Liversidge et al.	8/7/2001	
	A 2 3 6	6274633		Franks et al.	8/14/2001	
	A 2 3 7	6281175		Lyons et al.	8/28/2001	
	A 2 3 8	6288040		Müller et al.	9/11/2001	
	A 2 3 9	6288127		Bienlarz et al.	9/11/2001	
	A 2 4 0	6294191		Meers et al.	9/25/2001	
	A 2 4 1	6294192		Patel et al.	9/25/2001	
	A 2 4 2	6297985		Kang	10/2/2001	
	A 2 4 3	6309623		Weers et al.	10/30/2001	
	A 2 4 4	6312715		Cantor et al.	11/6/2001	
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	A 2 4 6	6328708		Georgieff	12/11/2001	
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	A 2 5 9	2001/0007663		VON CORSWANT	7/12/2001	
	A 2 6 0	2001/0046474		Weers et al.	11/29/2001	

Examiner Signature	<i>[Signature]</i>	Date Considered	5/9/05
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet 9 of 13

Complete If Known	
Application Number	09/281,430
Filing Date	March 30, 1999
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Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

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Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
	A 261		DE 2 513 797		Imperial Chemical Industries (see reference 4,056,635)	10/9/1975		X*
	A 262		DE 2 938 807		Green Cross Corp.	11/13/1980		X*
	A 263		DE 3 421 468		Dr. Rentschler Arzne. (see reference 4,880,634)	12/19/1985		X*
	A 264		DE 4 440 337		Rainer H. Müller (see reference 5,858,410)	5/15/1996		X*
	A 265		EP 0 036 277		Regents/ Univ. California	3/6/1981		
	A 262		EP 0 052 322		Gersonde, Klaus	5/26/1982		X*
	A 267		EP 0 153 926		Duncan H. Haynes	6/14/1984		
	A 268		EP 0 272 091		Vestar, Inc.	6/22/1988		
	A 269		EP 0 330 532		Fournier Industrie (see reference 4,895,726)	1/30/1989		X*
	A 270		EP 0 355 095		Liposome Comp., Inc.	8/4/1988		
	A 271		EP 0 391 369		Yissum Research Devel., Co.	4/4/1990		
	A 272		EP 0 418 153		Medgenix Group, S.A. (see reference 5,100,591)	3/20/1991		X*
	A 273		EP 0 456 670		B. Braun Melsungen AG	11/18/1993		X*
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	A 276		EP 0 570 829		Dr. Hans Dietl (see reference 5,527,537)	5/12/1993		X*
	A 277		EP 0 580 690		Sandoz Ltd.	2/2/1994		
	A 278		EP 0 589 843		Sandoz AG	9/21/1993		
	A 279		EP 0 601 618		Sterling Winthrop Inc.	10/30/1993		
	A 280		EP 0 605 497		Rainer Müller (see reference WO 93/05769)	3/20/1996		X*
	A 281		EP 0 724 877		Laboratoires Fournier S.C.A. (see reference 5,880,148)	8/7/1996		X*
	A 282		EP 0 757 911		CL Pharma (see reference 5,827,536)	2/12/1997		X*
	A 283		EP 0 770 381		L'OREAL (see reference 5,827,520)	5/2/1997		X*
	A 284		EP 0 602 700		Sterling Winthrop Inc.	12/1/1993		

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Sheet 10 of 13

Complete if Known	
Application Number	09/281,430
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Group Art Unit	1615
Examiner Name	Todd Ware
Attorney Docket Number	402076 SKYEPHARMA

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Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
		Office	Application or Patent Number	Kind Code			Yes	No**
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	A 292		JP 55141407		A. Nattermann & Cie (see reference 4,309,421)	11/5/1980		X*
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	A 295		JP 63233915		Green Cross Corp. (see reference 5,320,906)	10/21/1985		X*
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	A 297		WO 00/10531		RTP Pharma Inc.	3/2/2000		
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Examiner Signature

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Sheet 11 of 13

FOREIGN PATENT DOCUMENTS

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		Office	Application or Patent Number	Kind Code			Yes	No**
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	A 3 1 3		WO 92/18105		Sandoz Ltd.	10/29/1992		
	A 3 1 4		WO 93/05768		Medac Gesellschaft	4/1/1993		
	A 3 1 5		WO 93/19736		Kabi Pharmacia	10/14/1993		
	A 3 1 6		WO 94/14415		Hemagen/PFC	7/7/1994		
	A 3 1 7		WO 94/20072		Pharmacia AB	9/15/1994		
	A 3 1 8		WO 94/26728		Chinoin Ltd.	11/24/1994		
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	A 3 3 1		WO 99/49846		RTP Pharma	10/7/1999		
	A 3 3 2		WO 99/49848		RTP Pharma	10/7/1999		

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Sheet

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of

13

Application Number

09/281,430

Filing Date

March 30, 1999

First Named Inventor

INDU PARIKH

Group Art Unit

1615

Examiner Name

Todd Ware

Attorney Docket Number

402076 SKYEPHARMA

OTHER - NON PATENT LITERATURE DOCUMENTS

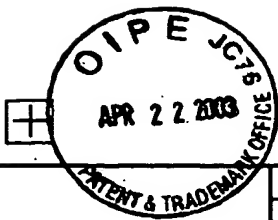
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
AK	A 333	[LSP4]La Fuma Polymery 1998 43 nr 2, 104-108, "The role of water-soluble polymers at the solid/liquid etc."		
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Examiner Signature	<i>[Signature]</i>	Date Considered	5/9/03
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Sheet	13	of	13
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C mplet if Known	
Application Number	09/281,430
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OTHER - NON PATENT LITERATURE DOCUMENTS

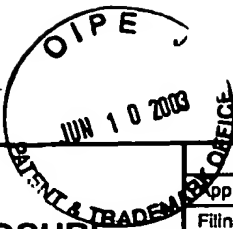
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	A 351	HERBERT A. LEIBERMAN and LEON LACHMAN, Eds., <i>Pharmaceutical Dosage Forms, Tablets, Vol. 1, (1980), p. 13</i>		
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Substitute for form 1449A/B/PTO <h2 style="text-align: center;">INFORMATION DISCLOSURE STATEMENT BY APPLICANT</h2> <p style="text-align: center;">(Use as many sheets as necessary)</p>		<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <th colspan="2" style="text-align: left;">Compleat if Known</th> </tr> <tr> <td style="width: 50%;">Application Number</td> <td>09/281,430</td> </tr> <tr> <td>Filing Date</td> <td>March 30, 1999</td> </tr> <tr> <td>First Named Inventor</td> <td>PARIKH</td> </tr> <tr> <td>Group Art Unit</td> <td>1615</td> </tr> <tr> <td>Examiner Name</td> <td><i>Twane Carlos Arpura</i></td> </tr> <tr> <td>Attorney Docket Number</td> <td>402076/SkyePharma</td> </tr> </table>		Compleat if Known		Application Number	09/281,430	Filing Date	March 30, 1999	First Named Inventor	PARIKH	Group Art Unit	1615	Examiner Name	<i>Twane Carlos Arpura</i>	Attorney Docket Number	402076/SkyePharma
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Sheet	1	of	5														

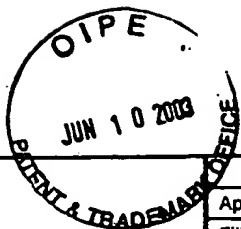
U.S. PATENT DOCUMENTS						
Examiner Initials	Doc. No.	U.S. Patent Document		Name of Patentee or Applicant	Date of Publication	Filing Date If Appropriate
		Application or Patent Number	Kind Code			
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Examiner Initials	Doc. No.	Foreign Patent Document			Name of Patentee or Applicant	Date of Publication	Translation	
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OK	12 ✓	EP	314 060		Warner-Lambert Co.	5/3/89		
	13 ✓	EP	539 319		Novartis AG	4/28/93		
	14 ✓	EP	589 843		Sandoz AG	3/30/94		
	15 ✓	EP	636 618		Marigen S.A.	2/1/95		X+
	16	EP	670 715		Gattefosse S.A.	9/13/95		X+
	17	EP	760 237		CIPLA Ltd.	3/5/97		
	18 ✓	UK	2 217 173		B A Whittle	10/25/89		
	19 ✓	WO	94/08603		Smith-Kline Beecham Corp.	4/28/94		
	20	WO	94/08605		Smith-Kline Beecham Corp.	4/28/94		
	21 ✓	WO	94/23733		DR. Rentschler Arzenemittel GMBH & Co.	10/27/94		X+
	22 ✓	WO	94/25068		Sherman	11/10/94		
	23 ✓	WO	95/11039		Hexal Pharma GMBH	4/27/95		X+
	24	WO	95/33490		Enzon, Inc.	12/14/95		
	25	WO	96/13273		Sandoz Ltd.	5/9/96		
	26	WO	96/35415		Sime et al.	11/14/96		
	27	WO	97/00080		Hexal AG	1/3/97		X+
	28	WO	97/02042		GS Development AB	1/23/97		
	29	WO	97/12626		Dietl	4/10/97		X+
	30	WO	97/19692		Sandoz-Patent-GMBH	6/5/97		
	31	WO	97/22358		Sherman	6/26/97		
32	WO	97/25977		Novartis AG	7/24/97			
33	WO	97/26003		Galena A S	7/24/97			
34	WO	97/36610		Chong Kun Dang Corp.	10/9/97			

Examiner Signature <i>[Signature]</i>	Date Considered <i>5/9/05</i>
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Substitute for form 1449A/B/PTO			Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)			Application Number	09/281,430	
			Filing Date	March 30, 1999	
			First Named Inventor	PARIKH	
			Group Art Unit	1615	
			Examiner Name	T. Ware Carlos A. 2	
Sheet	2	of	5	Attorney Docket Number	402076/SkyePharma

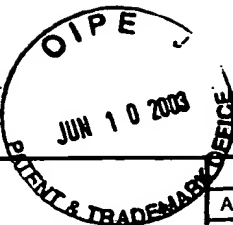
OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
CA	35	Ardulno, M.J. et al., "Microbial Growth and Endotoxin Production in the Intravenous Anesthetic Propofol", Infection Control and Hospital Epidemiology, Vol. 12, No. 9, September 1991, pp. 535-539.		
	36	Attwood, David, "Microemulsions," Colloidal Drug Delivery Systems, © 1994, pp. 31-33.		
	37	Babl et al., "New Formulations of Propofol in an LCT/MCT Emulsion: Approach to Reduce Pain on Injection", Eur. Hosp. Pharmacy, January 1995, Vol. 1, No. 1, pp. 15-21.		
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	39	Cairns et al., "Tolerance of Mixed Lipid Emulsion in Neonates: Effect of Concentration", Archives of Disease in Childhood, (1996), Vol. 75, p. F113-F116.		
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	41	Cox et al., "Influence of Different Fat Emulsion-Based Intravenous Formulations on the Pharmacokinetics and Pharmacodynamics of Propofol," Pharmaceutical Research, (1998) Vol. 15, No. 3, pp. 442-48.		
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CA	51	Freeman, Andrew B., "A Technique for Reducing Pain Associated with Propofol Administration," Anesth. Analg., 1992 (1 page).		

Examiner Signature		Date Considered	5/9/03
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
Sheet	3	of	5	Application Number	09/281,430
				Filing Date	March 30, 1999
				First Named Inventor	PARIKH
				Group Art Unit	1615
				Examiner Name	<u>I. Ware Carlos</u>
				Attorney Docket Number	402076/SkyePharma

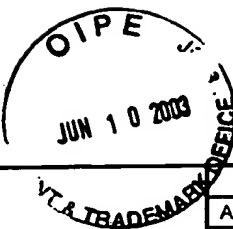
OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
	52	Ghouri et al., "Effect of Flumazenil on Recovery after Midazolam and Propofol Sedation", Anesthesiology, (1994), Vol. 81, pp. 333-339.		
	53	Gottardis et al., Effect of Prolonged Sedation with Propofol on Serum Triglyceride and Cholesterol Concentrations, British J. Anaesthesia, (1989) Vol. 62, pp. 393-396.		
	54	King et al., "Lidocaine for the Prevention of Pain Due to Injection of Propofol", Anesth. Analg. (1992), Vol. 74, pp. 246-249.		
	55	Lindholm, Marianne, "Critically Ill Patients and Fat Emulsions," Minerva Anesthesiology, (1992), Vol. 58, No. 10, pp. 875-879.		
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	64	Stark, et al., "A review of the safety and tolerance of propofol ('Diprivan')", Postgraduate Medical Journal, 1985, Vol. 61, Suppl. 3, pp. 152-156.		
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	67	Tarr et al., "A New Parenteral Emulsion for the Administration of Taxol," Pharmaceutical Research, Vol. 2 No. 2, 1987, pp. 162-165.		

Examiner Signature		Date Considered	<u>5/9/05</u>
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Substitute for form 1449A/B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
Sheet	4	of	5	Application Number	09/281,430
				Filing Date	March 30, 1999
				First Named Inventor	PARIKH
				Group Art Unit	1615
				Examiner Name	J. Ware <i>Carlo</i>
				Attorney Docket Number	402076/SkyePharma

OTHER - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Doc. No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number (s), publisher, city and/or country where published.	Translation	
			Yes	No**
CA	68	Tessler et al., "Growth curves of <i>Staphylococcus aureus</i> , <i>Candida albicans</i> , and <i>Moraxella osloensis</i> in propofol and other media", <i>Can. J. Anaesth.</i> (1992), Vol. 39 No. 5, pp. 509-511.		
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	75	Sjöström, et al., "A Method for the Preparation of Submicron...and Surfactant Concentration", <i>J. of Pharmaceutical Sciences</i> , Vol. 82, No. 6, pp. 579-583, (June 1993).		
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	80	Groves et al., "Rheological characterization of self-emulsifying oil/surfactant systems", <i>Acta Pharm. Suecica</i> , Vol. 13, pp. 353-360, (1976).		
MA	81	Eugster, et al., "Marigenol® Concentrates comprising Taxol and/or Taxan esters as active substances", <i>Panminerva Med.</i> , Vol. 38, pp. 234-242, (1996).		

Examiner Signature		Date Considered	<i>5/4/03</i>
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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Application Number	09/281,430
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Filing Date	March 30, 1999
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First Named Inventor	PARIKH
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Group Art Unit	1615
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Examiner Name

Attorney Docket Number	402076/SkyePharma
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Translation

Yes

No⁺

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Gershanik, et al., "Positively Charged Self-Emulsifying Oil Formulation for Improving Oral Bioavailability of Progesterone", Pharm. Dev. * Tech., Vol. 1, No. 2, pp. 147-157, (1996).

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Constantinides, P., et al. "Formulation and Intestinal AbsorptionMedium-Chain Glycerides", Pharm. Research, Vol. 11, No. 10, pp. 1385-1390, (1994).

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**Examiner
Signature**

Date
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